REMARKS

Status of the Claims

Claims 1 to 12, and 17 to 20 were amended in connection with this Reply. Claims 13 to 16 were previously presented. No claims have been added, withdrawn or cancelled. Accordingly, presented herein are claims 1 to 20 for the Examiner's consideration. References herein to cites in the specification refer to line and page numbers found in the originally published PCT application.

Amendment to Claim 1 is supported by the specification, regarding propensity for overweight, on Page 8, first Table presented therein in connection with Example 1, and respecting BMI, on page 3 at lines 23 to 27 and page 4 at lines 1 to 17.

Amendment to Claim 2 is supported by the specification on page 5 at lines 9 to 14.

Claim 3 was amended to accord with amendments to Claim 1 and is supported by the original text of Claim 3.

Amendment to Claim 4 is supported by the specification on page 4 at lines 4 to 8.

Claims 5 and 6 were amended for clarity, no support is needed.

Amendments to Claim 7 as to the sole antipsychotic agent and kit are supported by the specification on page 5 at lines 31 to 35, and with regard to the definition of BMI and the BMI value recited, by the specification, first table on Page 8, example 1, on page 3, at lines 23 to 27 and on page 4 at lines 1 to 17.

Claims 8 to 12 and 17 to 20 were amended to accord with the claims from which they depend, no support is needed for this amendment.

Rejection Under 35 U.S.C. § 112

The present Action rejects claims 7 to 20 under 35 U.S.C. §112 on the grounds that the claims are indefinite and under 35 U.S.C. §101 on the grounds that no process for use is set forth in the claim. Applicants are puzzled by the citation to 35 U.S.C. §101 in the present Action since that section of the law is directed to defining who is entitled to a patent for an invention and mentions "process" only in terms that it is acceptable subject matter for a patent.

Regarding the 35 U.S.C. §112 rejection, Applicants point out that claims 13 to 16 depend from claims 2 to 5, and the present Action has not found these claims to be indefinite. Accordingly, claims 13 to 16 only serve to further limit the claims from which they depend, to a specific route of administration, which is a well known route of administration described in the literature (see for example, the Delbressine patent which is cited in the specification of the present application and in the present Action in support of an obviousness rejection). Moreover, sublingual administration is generally well know in the medical arts without the need for detailed recitation of "steps" by which it may be accomplished. Applicants believe that the Action is in error in asserting that these claims are indefinite, and the Examiner is requested to reconsider these claims and withdraw the rejection or clarify in what manner they are indefinite and reissue the Action. Moreover, Applicants assert that the Rejection under 35 U.S.C. 101 is in error, since applicants have discovered a new and useful process for mitigating a nearly universal problem seen in the treatment of schizophrenia in selected (obese or with a propensity toward obesity) patients using asenapine, and are therefore entitled to a patent, other factors being shown.

Claims 7 to 12 and 17 to 20 have been amended to indicate that they pertain to a kit for use in a method of treatment described by claims 1 to 6 and 13 to 16. These amendments make clear that the kit contains labeling regarding the method of treatment and this kit is used in connection with treating a disease and avoiding concomitant complications (causing or increasing obesity) associate with treating that disease. The specification clearly defines the term "treating" on page 2, beginning at line 17, which comprises administration of the medicament. Accordingly, Applicants believe that these amendments overcome the asserted §112 rejection. As for claims 13 to 16, Applicants believe that citation of a rejection under 35 U.S.C. §101, which the Action states is predicated upon the claim reciting "a use for" without specifying particular process steps is in error as applied to these claims since the statute cited is silent on this matter. However, in the interest of moving the application forward, these claims have been amended as mentioned above, and in view of the amendment, a rejection pursuant to 35 U.S.C. §101 seems to be moot. Accordingly, in view of the foregoing Amendments and Remarks Applicants respectfully request that the Examiner

enter the amendments, withdraw the rejections pursuant to 35 U.S.C. §101 and 35 U.S.C. §112 and pass these claims into allowance.

Rejection Under 35 U.S.C. § 103(a)

The present action has Rejected claims 1 to 6 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,763,476 (the '476 patent) in view of U.S. Patent No. 5,763,831 (the '831 patent) in combination with an article by L.J. Aronne published in J. Clin. Psychiatry 2001, 62 (suppl 23), (the Aronne publication).

The '476 patent describes a sub-lingual dosage form containing asenapine for the treatment of psychotic disorders, including schizophrenia. It does not discuss any side effects associated with such treatment. The '831 patent describes a method of treating insulin-stimulated obesity by administering rapamycin. It does not describe or suggest anything regarding any antipsychotic drug or the use thereof in treating schizophrenia, or any side-effects associated with the use of any antipsychotic drug. The Aronne publication describes the "epidemic" level of the occurrence of obesity in the U.S. human population and defines obesity in terms of body mass index. The Aronne publication mentions that obesity is a side-effect associated with the administration of antipsychotic drugs (see page 14, second paragraph under heading "Epidemiology" and page 17, last paragraph left column through first paragraph page 17 right column and Figure 8 therein). The Aronne publication also discusses two drugs which have been approved for the treatment of obesity (see paragraphs under heading "Pharmacotherapy" beginning on page 19). In discussing these available treatment options the Aronne publication states that neither of the treatment options described have been found to be safe or effective for use by those taking antipsychotic drugs.

The present Action states that in view of the cited art, it would have been obvious to address comorbidity in schizophrenic patients by administration of asenapine. Neither the '476 patent nor the '831 patent offer any information addressing weight gain in treating patients with antipsychotic medications. The Aronne publication discloses that 86% of all antipsychotic drugs (7 out of 8 tested) and 80% of atypical antipsychotic drugs (4 out of 5 atypical antipsychotic drugs tested) actually promote obesity when patients are treated with those drugs (see Table 8, page 17 therein). There is simply no connection between the property discovered by the inventors, that weight gain is substantially non-existent in patients treated with asenapine and the cited articles, in fact the Aronne article suggests that you have nearly a 90% chance of inducing obesity in treating humans with any antipsychotic drug. The present Action has not shown a nexus between the proposition that it would have been obvious to obtain the results described in the present application and the information disclosed in the cited references. Neither has the Action described or provided evidence that such knowledge is within the ordinary skill of the art. The fact that many popular antipsychotic drugs are

sold today which have as a side effect inducing or increasing obesity in patients treated with them suggests that it is not within the ordinary level of skill to examine antipsychotic agents and understand those that will or will not induce or increase obesity when administered to a patient.

In view of the Amendments presented herein and the foregoing arguments the Examiner is respectfully requested to enter the amendments, reconsider the claims, withdraw the obviousness rejection and pass the application into allowance.

MISCELLANEOUS

This is a Reply to an Action mailed June 15, 2009, with a three month initial period for Reply ending on September 15., 2009. As this Reply is being submitted electronically on December 15, 2009, a three-month extension of the period, from September 15, 2009 to December 15, 2009, is requested. The commissioner is authorized to charge the fee for the three month extension of time pursuant to 37 C.F.R. §1.17(a)(3), believed to be $1110.00, to Applicants' Deposit Account No. 50-4205. No other fees are believed to be due in connection with this Reply, however should it be deemed that any additional fees are necessary, the Commissioner is authorized to charge the amount thereof to Applicants' Deposit Account No. 50-4205.

It is believed that the foregoing is fully responsive to the outstanding Action. The Examiner is invited to call the undersigned attorney on any outstanding matter connected with this application.

December 15, 2009
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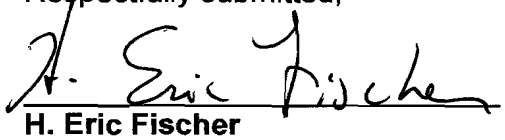
Respectfully submitted,



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